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Andie Denious, MS, RN

Special Projects Coordinator

The Arizona Partnership for Immunization (TAPI)

andied@tapi.org



To Err Is Human; Not To Err Is Better!

Vaccination Errors and How to Prevent Them

Deborah L. Wexler, MD
Immunization Action Coalition
deborah@immunize.org
National Immunization Conference
Atlanta, Georgia
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(Revised 11/12, 12/13)



**With thanks to
Donna L. Weaver, RN, MN**

**National Center for Immunization and Respiratory
Diseases, CDC**

and Teresa A. Anderson, DDS, MPH

Types of vaccination errors

- **Storage and handling**
- Administration
- Scheduling
- Documentation

Vaccine storage and handling



- Vaccines are fragile and must be kept at recommended temperatures at all times
- Vaccines are expensive
(Example - PCV13 - \$112.44/\$135.80/DOSE!)

- It is better NOT TO VACCINATE rather than administer a dose of vaccine that has been mishandled.

The results of storage and handling errors

- You lose a lot of money
- You must revaccinate anyone who received a dose of compromised vaccine
- You will have to explain to irate parents why their children must repeat the vaccine doses
- The media will find out and provide your practice with negative publicity

Newspaper Headlines



Is any publicity really good publicity?

“1,900 doses of flu vaccine spoil in hospital’s faulty fridge”

(West Allis, WI; 11/3/04)

“Kaiser mishandles flu vaccine” (Fresno, CA; 12/15/04)

“Storage errors cause thousands to be vaccinated again”

(Knoxville, TN; 1/21/05)

“U.S. doctor accused of giving last year’s flu vaccine”

(Bellingham, WA; 11/6/04)

“Frozen vaccine could cost state more than \$30,000”

(Arkansas; 11/19/04)

From our IAC email archive...

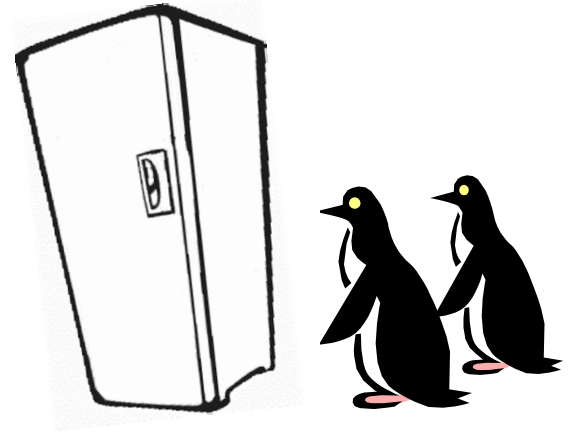


HELP!



HELP! “We have a local practice that had issues with their refrigerator temperatures being too cold for an extended period. All the vaccines that were given during that time frame are now considered invalid. They have many 2-year-old patients who received 4 doses of DTaP all of which were stored improperly...”

How to avoid storage & handling problems



- Assign a vaccine manager & backup
- Store all vaccines appropriately
- Monitor and record refrigerator and freezer temperatures twice daily and review the results twice a day
- Use only certified calibrated thermometers
- Maintain temperature logs for 3 years
- Implement a vaccine emergency system
- Take immediate action for out-of-range temps.
- **DO NOT STORE ANYTHING ELSE** in the refrigerator

Vaccine handling basics

- Open only one box of each vaccine at a time
- Store vaccines separately from other medications or biologics
- Do **NOT** store food/beverages in the vaccine refrigerator or freezer
- Keep all vaccines (especially light sensitive vaccines) in their boxes until ready to use. Once opened, keep all vaccines in their boxes with lids & ends closed
- Rotate your stocks so vaccines never become outdated



HELP! “Can you advise as to the safety and efficacy of drawing up flu vaccine ahead of time for mass vaccination clinics. One place I work is using vaccines drawn from a multidose vial as much as a week before actually giving the vaccine.”

Prefilling syringes?

- This practice is strongly discouraged by CDC
- May result in vaccine administration errors
- May consider in situations of heavy use of a single vaccine (e.g., annual influenza clinic)
- Consider using manufacturer-supplied prefilled syringes
- Syringes other than those filled by manufacturer should be discarded at end of clinic day. Also, manufactured pre-filled syringes that have had the caps removed and a needle attached to the syringe should be discarded at the end of the day.

Adapted CDC

Live virus vaccines and some inactivated vaccines must be administered promptly after reconstitution...

**If not administered within the time limit, these vaccinations must be repeated!
(If live virus vaccine, there is a 4-week minimum interval.)**

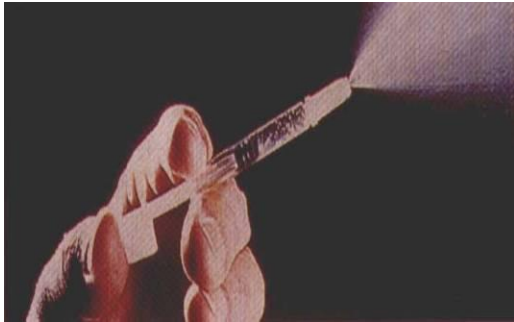
Time limits for using vaccines after reconstitution

- Varicella ≤ 30 mins (and protect from heat & light)
- Zostavax ≤ 30 mins (and protect from heat & light)
- MMRV ≤ 30 mins (and protect from heat & light)
- Yellow fever ≤ 1 hour
- MMR ≤ 8 hours (and protect from heat & light)
- Menomune single dose vial ≤ 30 mins

Types of vaccination errors

- Storage and handling
- **Administration**
- Scheduling
- Documentation

Administering vaccines correctly



- **Ensure your staff is adequately trained**
- **Provide current immunization education**
- **Adhere to OSHA guidelines for employee safety**
- **Provide staff with easy to use resources and guidelines**



Types of Administration Errors

- Wrong vaccine or diluent
- Wrong dosage
- Expired vaccine
- Incorrect route/site/needle size

A study using the largest medication error reporting database in the U.S. found that administration of the wrong vaccine was the commonly reported error.

Such errors usually involved vaccines whose generic or trade names looked or sounded alike (Tdap/DTaP, Adacel and Daptacel), or which have similar packaging.

Vaccine (2009)27:3890-6

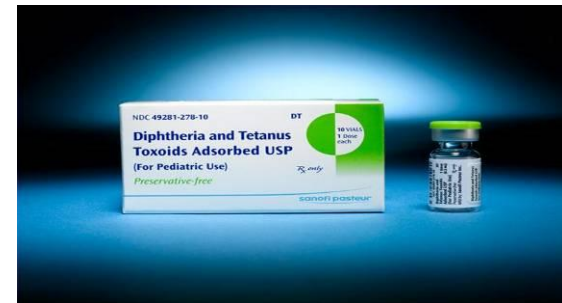
Similar Packaging

Check the vial 3 TIMES

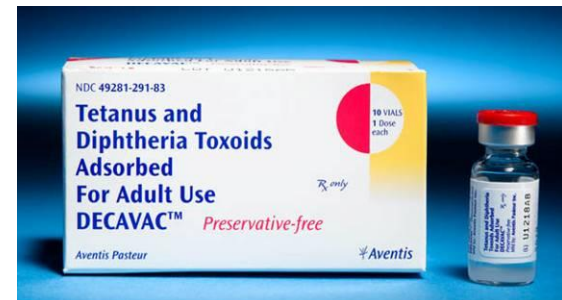
- PPD
(tuberculin skin test)



- DT



- Td



Is it
Tdap
DTaP
or Td?

Check Your Vials: is it Tdap DTaP or Td?

Tdap: Tetanus, Reduced Diphtheria, Acellular Pertussis

Preteens - Adults

ADACEL™ (sanofi pasteur)
Ages 11-64 years




Boostrix® (GlaxoSmithKline)
Ages 10-64 years




DTaP: Diphtheria, Tetanus, Acellular Pertussis

Infants - Young Children

DAPTACEL® (sanofi pasteur)
Ages 6 weeks up to 7 years




Infanrix® (GlaxoSmithKline)
Ages 6 weeks up to 7 years




TRIPEDIA® (sanofi pasteur)
Ages 6 weeks up to 7 years




Pediarix® (GlaxoSmithKline)
Ages 6 weeks up to 7 years




Pentacel® (sanofi pasteur)
Ages 6 weeks up to 5 years




Kinrix® (GlaxoSmithKline)
Ages 4 years through 6 years




Td: Tetanus, Diphtheria

Td (sanofi pasteur)
Ages 7 years and older




Age Indications for use of products in the VFC program may differ from age indications on this guide or in the package inserts. Not all formulations are available from the VFC Program.
Questions: Toll-free: 877-2Get-VFC (877-243-8832)

California Department of Public Health, Immunization Branch MM-500 (6/09)

Check
the vial
3 times!

immunization
action coalition
IAC
immunize.org

HELP! What to do about DTaP and Tdap errors

Error

Action

DTaP given to person
≥7yrs

Count dose as valid

Tdap given to child
<7yrs as DTaP #1, 2, or 3

Do not count dose;
give DTaP now

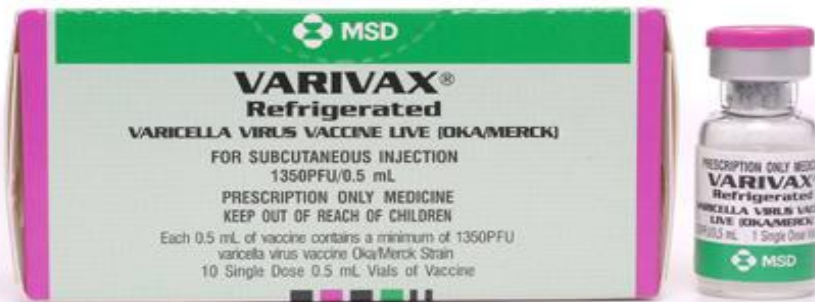
Tdap given to child <7yrs as
DTaP #4 or 5

Count dose as valid

Tdap given to child 7-9yrs

Count dose as valid

Another source of confusion: varicella-containing vaccines



Varivax
(12 mos of age and older)



ProQuad MMRV (12 mos thru 12 yrs)



Zostavax

(60 yrs of age and older)



HELP! “One of the nurses who works in one of our hospital’s primary care clinics gave Zostavax vaccine to a 1-year-old. She knew it wasn’t Varivax, but the physician told her it was ‘basically the same’ and to give it. I know this was a HUGE medication error, but does the dose count?”

ANSWER

Yes, this is a serious vaccine administration error. The event should be documented as a vaccine error and procedures put in place to prevent this from ever happening again. Zostavax vaccine contains about 14 times as much varicella vaccine virus as Varivax. The dose should be counted as valid.



HELP! “A 60-year-old patient was given varicella vaccine instead of zoster vaccine. Should the patient still be given the zoster vaccine? If so, how long an interval should occur between the 2 doses?”

ANSWER

The dose is not valid and the patient should receive a dose of zoster vaccine during that same visit. If the error is not immediately detected, a dose of zoster vaccine should be administered as soon as possible but not within 28 days of the varicella vaccine dose to prevent potential interference of 2 doses of live attenuated virus.

AVOID ERRORS

Check the vial 3 TIMES!!!

Another potential problem... using the wrong diluent

Vaccine + Diluent

M-M-R[®] II + Sterile water

Varivax[®] + Sterile water

ProQuad[®] = MMRV +
Sterile water

Zostavax[®] + Sterile water

ActHIB[®] + 0.4% Sodium
chloride

Menomune[®] + Distilled water



HELP! “One of the nursing staff used the Merck sterile water diluent to reconstitute the ActHib instead of the 0.4% sodium chloride that comes with it. Does it need to be repeated or will it be considered okay?”

ANSWER

If the wrong diluent is inadvertently used, the immunization must be repeated. The only exception is MMR and MMRV--the diluent is the same (sterile water) and made by the same company.

Giving the wrong vaccine will rarely cause a serious problem, but...

- **Additional doses can lead to more vigorous local reactions**
- **Patient may be left unprotected against disease**
- **Additional cost**
- **Inconvenience to patient/parent**
- **May cause loss of faith in provider or complaint to state board**



HELP! “Yesterday my 18-month-old’s pediatrician informed me that they made a mistake with her vaccines. They gave her two doses of Prevnar and did not vaccinate for Hib. Will this harm my child? Do I need to get a lawyer and attack this incompetent practice? I am very concerned for my child and the impact it could have on her.”

Another administration error: giving the wrong dose

HELP! “If an adult patient got a child’s dose of hepatitis B vaccine, should he be given an adult dose? If so, how soon?”

HELP! “We had an incident recently where a 5-year-old presented for ‘catch up immunizations’ but was given an adult dose of hep A. We are wondering about side effects or other possible issues.”

If you give **less** than a full age-appropriate dose of any vaccine, the dose is **invalid**. You should revaccinate the person with the appropriate dose as soon as feasible. Exceptions are if a patient sneezes after nasal spray vaccine or an infant regurgitates, spits, or vomits during or after receiving oral rotavirus vaccine.

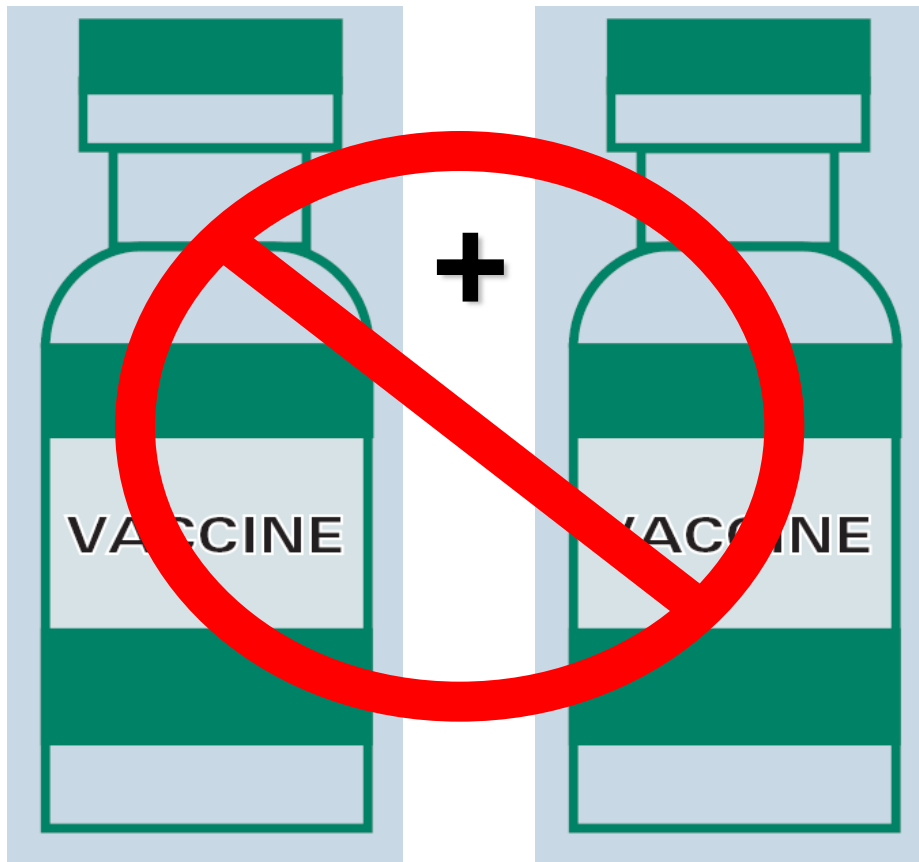
If you give **more** than an age-appropriate dose of a vaccine, count the dose as **valid** and notify the patient/parent about the error. Using larger than recommended dosages can be hazardous because of excessive local or systemic concentrations of antigens or other vaccine constituents.

Another dosage error: split or partial doses



- Split or partial (incomplete) doses are **NOT VALID** doses. This includes situations where the patient moves before the injection is completed.
 - Exceptions to partial doses
 - LAIV if person sneezes
 - Rotavirus if infant regurgitates, spits out, or vomits

Another administration error: combining vaccines



Vaccines should **NEVER** be combined in the same syringe unless FDA approved for this purpose.

Another administration error: using expired vaccine

Vaccine Expiration Date:

8/15/06

Note Use through
August 15, 2006. Do
NOT use on or after
August 16, 2006



Vaccine Expiration Date:

8/06

Note Use through
August 31, 2006. Do
NOT use on or after
September 1, 2006

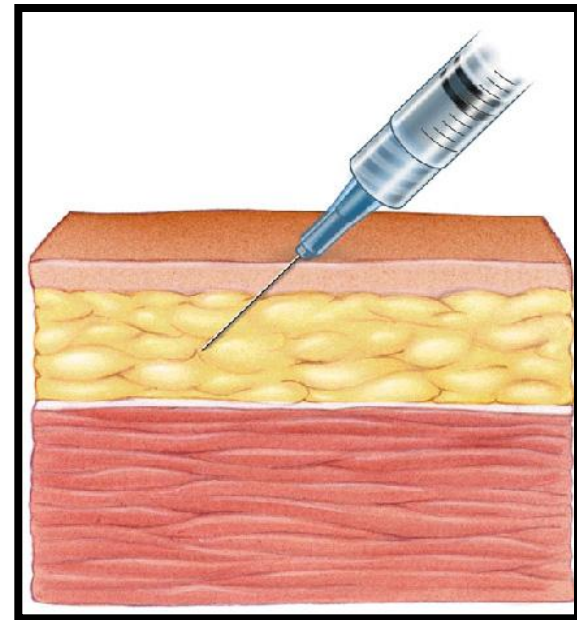
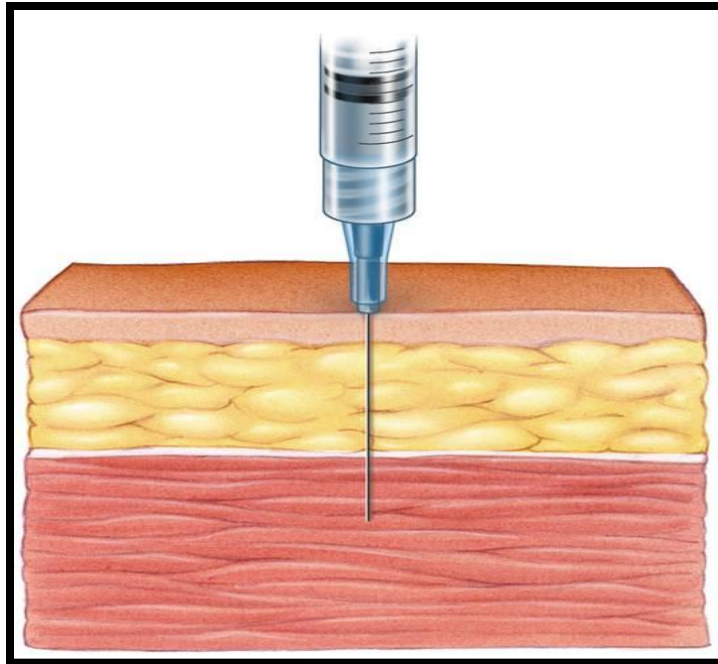


HELP! “A physician just called and gave a child a dose of expired vaccine. I am assuming the dose should be re-administered. Please advise.”

ANSWER

The dose should be repeated. If the expired dose is a live virus vaccine, you must wait at least 4 weeks after the expired dose was given before repeating it. The repeat dose of an expired inactivated vaccine can be given on the same day or any other time. If you prefer, you can perform serologic testing to check for immunity for certain vaccinations (e.g., measles, rubella, hepatitis A, and tetanus).

Another administration error: incorrect route, site, or needle size



HELP! “One of our nurses accidentally gave Zostavax IM instead of SC. Can you tell me what we need to do?”

ANSWER

Vaccines should always be given by the route recommended by the manufacturer. However, ACIP recommends that vaccines given by the wrong route be counted as valid with two exceptions: **hepatitis B or rabies vaccine** given by any route other than IM (and in the deltoid or anterolateral thigh muscle) should not be counted as valid and should be repeated.

Types of vaccination errors

- Storage and handling
- Administration
- **Scheduling**
- Documentation

Scheduling errors: giving doses at too young an age

- Giving the 1st dose of MMR before age 12 months
- Giving the 3rd dose of Comvax before age 12 months
- Giving the 4th dose of DTaP before age 12 months or less than 6 months after 3rd dose
- Finishing infant's hepB series before 24 wks
- Giving any vaccine (except hepatitis B) before age 6 weeks



HELP! “While registering her for kindergarten, it was brought to my attention by the school RN that my daughter's initial MMR vaccine may not be valid. She received this dose 25 days before her first birthday. I do not want to re-administer a 3rd vaccine if it is not necessary. It is painful and excessive. What, if any, steps can I take to avoid re-vaccinating my daughter?”

Scheduling errors: giving doses without the minimum spacing

- Giving 2nd dose of hepatitis A vaccine less than 6 months after the first dose
- Giving the hep B vaccine series without at least 4 wks between doses 1 and 2; 8 wks between doses 2 and 3; and 16 wks between doses 1 and 3.
- Giving the HPV vaccine series without at least 4 wks between doses 1 and 2; 12 wks between doses 2 and 3; and 24 wks between doses 1 and 3.

The 4-day “Grace Period”

Vaccine doses administered up to 4 days before the minimum interval or age can be counted as valid.

This grace period should not be used when scheduling future vaccination visits, or applied to the 28-day interval between live parenteral vaccines of two different vaccines not administered at the same visit.

Use of the grace period may conflict with state daycare or school entry vaccination requirements.

Doses administered 5 or more days before the **minimum age** should be repeated on or after the patient reaches the minimum age and 4 or more weeks after the invalid dose.

Doses administered 5 or more days earlier than the recommended **minimum interval** between doses are not valid and must be repeated. The repeat dose should be spaced after the invalid dose by the recommended minimum interval.

A clinician's best friend...

CDC's "Recommended and Minimum Ages and Intervals Between Doses of Routinely Recommended Vaccines"

<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval-table.pdf>

Recommended and Minimum Ages and Intervals Between Doses of Routinely Recommended Vaccines ¹				
Vaccine and dose number	Recommended age for this dose	Minimum age for this dose	Recommended interval to next dose	Minimum interval to next dose
Hepatitis B (HepB)-1 ²	Birth	Birth	1-4 months	4 weeks
HepB-2	1-2 months	4 weeks	2-17 months	8 weeks
HepB-3 ³	6-18 months	24 weeks	—	—
Diphtheria-tetanus-acellular pertussis (DTaP)-1 ²	2 months	6 weeks	2 months	4 weeks
DTaP-2	4 months	10 weeks	2 months	4 weeks
DTaP-3	6 months	14 weeks	6-12 months ⁴	6 months ^{4,5}
DTaP-4	15-18 months	12 months	3 years	6 months ⁴
DTaP-5	4-6 years	4 years	—	—
<i>Haemophilus influenzae</i> type b (Hib)-1 ^{1,6}	2 months	6 weeks	2 months	4 weeks
Hib-2	4 months	10 weeks	2 months	4 weeks
Hib-3 ⁷	6 months	14 weeks	6-9 months ⁴	8 weeks
Hib-4	12-15 months	12 months	—	—
Inactivated poliovirus (IPV)-1 ²	2 months	6 weeks	2 months	4 weeks
IPV-2	4 months	10 weeks	2-14 months	4 weeks
IPV-3	6-18 months	14 weeks	3-5 years	6 months
IPV-4	4-6 years	4 years	—	—
Pneumococcal conjugate (PCV)-1 ⁶	2 months	6 weeks	2 months	4 weeks
PCV-2	4 months	10 weeks	2 months	4 weeks
PCV-3	6 months	14 weeks	6 months	8 weeks
PCV-4	12-15 months	12 months	—	—
Measles-mumps-rubella (MMR)-1 ⁴	12-15 months	12 months	3-5 years	4 weeks
MMR-2 ⁴	4-6 years	13 months	—	—
Varicella (Var)-1 ²	12-15 months	12 months	3-5 years	12 weeks ⁸
Var-2 ⁸	4-6 years	15 months	—	—
Hepatitis A (HepA)-1 ¹	12-23 months	12 months	6-18 months ⁴	6 months ⁴
HepA-2	18-41 months	18 months	—	—
Influenza, Inactivated (TIV) ¹⁰	6-59 months	6 months ¹¹	1 month	4 weeks
Influenza, Live attenuated (LAIV) ¹⁰	—	2 years	1 month	4 weeks
Meningococcal Conjugate (MCV)	11-12 years	2 years	—	—
Meningococcal Polysaccharide (MPSV)-1	—	2 years	5 years ¹²	5 years ¹²
MPSV-2 ¹³	—	7 years	—	—
Tetanus-diphtheria (Td)	11-12 years	7 years	10 years	5 years
Tetanus-diphtheria-acellular pertussis (Tdap) ¹⁴	≥11 years	10 years	—	—
Pneumococcal polysaccharide (PPSV)-1	—	2 years	5 years	5 years
PPSV-2 ¹⁵	—	7 years	—	—

Other scheduling errors

- Giving rotavirus vaccine after 8 months 0 days
- Giving PPSV every 5 years
- Not allowing 6 months between the next-to-last and last doses of IPV
- Using Kinrix® for other than the 5th dose of the DTaP and the 4th dose of IPV in children age 4-6 years
- Giving live vaccines not administered at the same visit less than 4 weeks apart



HELP! “A client received an MMR vaccine at one clinic, and 7 days later received varicella vaccine at another clinic. I assume the varicella is not valid. What about the MMR?”

ANSWER

If two live virus vaccines are administered less than 4 weeks apart and not on the same day, the vaccine given second should be considered invalid and repeated. The repeat dose should be administered at least 4 weeks after the invalid dose. Alternatively, one can perform serologic testing to check for immunity, but this option may be more costly.

And the classic...

**re-starting a vaccine series because
of a longer-than-recommended
interval**

IMPORTANT RULE:

Vaccine doses should not be administered at intervals less than the recommended minimal intervals or earlier than the minimal ages.

**But, there is no maximum interval!
(Except for oral typhoid vaccine in some circumstances.)**

Types of vaccination errors

- Storage and handling
- Administration
- Scheduling
- **Documentation**

Types of documentation errors

- Not providing a VIS every time a vaccine is given
- Not using the most current VIS
- Not knowing if written consent is required
- Not recording all needed information in the patient's chart

HELP! “My 2 month old child was recently inoculated at his pediatrician’s office. The day following the immunizations my son spiked a high fever and I was extremely concerned. I called our local hospital and found out that I should have been given a VIS sheet for each of the inoculations that my child received. I did bring this matter up with the pediatrician’s office and I was told by the office manager that she didn’t know of any law that mandated they give information sheets out... My question is to whom do I report this incident? I no longer take my child to their office, but I want them to start doing things right.”

A minor side effect becomes a big problem because the parent wasn’t given a VIS...

How to ensure you are using the current VIS

- Check CDC's VIS web page
www.cdc.gov/vaccines/pubs/vis
- Check IAC's VIS web page
www.immunize.org/vis
- Subscribe to IAC Express and be notified of new and revised VISs and translations every Tuesday
www.immunize.org/subscribe



HELP! “For a child, do we have the parent sign each time we give a vaccine in a series or is it enough to have them sign for the first one?”

ANSWER

There is no federal law requiring written consent to vaccines. VISs cover both benefits and risks associated with vaccinations and they provide enough information that anyone reading them should be adequately informed. However, some states or institutions have informed consent laws. Check with your state immunization program and/or your institution. **NOTE: Arizona does require written consent**

Required information to document

- Type of vaccine e.g., MMR or Hib, NOT brand name
- Date given
- Manufacturer
- Vaccine lot #
- Name & address of practice/clinic
- Signature & title of individual administering the vaccine
- Date of the VIS
- Date the VIS was given to responsible person

Additional recommended information for AZ VFC providers:

- Vaccine source (Federal or State-supported or private)
- Site given (RLV, LVL, RD, LD, IN, ID, PO)
- VFC eligibility

Vaccine Administration Record for Children and Teens

Patient name: Shawn Abler

Birthdate: February 3, 2006

Chart number: SA-4837

Vaccine	Type of Vaccine ¹ (generic abbreviation)	Date given (mo/day/yr)	Source (F,S,P) ²	Site ³	Vaccine		Vaccine Information Statement		Signature/ initials of vaccinator
					Lot #	Mfr.	Date on VIS ⁴	Date given ⁴	
Hepatitis B⁵ (e.g., HepB, Hib-HepB, DTaP-HepB-IPV) Give IM.	HepB	2/03/06	S	RT	0651M	MRK	7/11/01	2/03/06	JTA
	Hib-HepB	4/03/06	S	RT	1051M	MRK	7/11/01	4/03/06	DCP
	Hib-HepB	6/05/06	S	RT	1051M	MRK	7/11/01	6/05/06	DCP
	Hib-HepB	2/05/07	S	LT	1106M	MRK	7/11/01	2/05/07	DCP
Diphtheria, Tetanus, Pertussis⁵ (e.g., DTaP, DTaP-Hib, DTaP-HepB-IPV, DT, DTaP-Hib-IPV, Tdap, DTaP-IPV, Td) Give IM.	DTaP	4/03/06	S	RT	647A2	GSK	7/30/01	4/03/06	DCP
	DTaP	6/05/06	S	RT	647A2	GSK	7/30/01	6/05/06	DCP
	DTaP	8/07/06	S	RT	647A2	GSK	7/30/01	8/07/06	DCP
	DTaP	5/07/07	S	RT	749B1	GSK	7/30/01	5/07/07	DCP
1 shot, 2 different VIS dates									
Hib-HepB (Comvax)									
Haemophilus influenzae type b⁵ (e.g., Hib, Hib-HepB, DTaP-Hib-IPV, DTaP-Hib) Give IM.	Hib-HepB	4/03/06	S	RT	1051M	MRK	12/16/98	4/03/06	DCP
	Hib-HepB	6/05/06	S	RT	1051M	MRK	12/16/98	6/05/06	DCP
	Hib-HepB	2/05/07	S	LT	1106M	MRK	12/16/98	2/05/07	DCP
Polio⁵ (e.g., IPV, DTaP-HepB-IPV, DTaP-Hib-IPV, DTaP-IPV) Give IPV SC or IM. Give all others IM.	IPV	4/03/06	S	LT	U4569-8	SPI	1/01/00	4/03/06	DCP
	IPV	6/05/06	S	LT	U4569-8	SPI	1/01/00	6/05/06	DCP
	IPV	4/03/07	S	LT	U4569-8	SPI	1/01/00	4/03/07	DCP
Pneumococcal (e.g., PCV, conjugate;	PCV	4/03/06	S	LT	489-835	WYE	9/30/02	4/03/06	DCP
	PCV	6/05/06	S	RT	489-835	WYE	9/30/02	6/05/06	DCP

How to avoid vaccine errors...

HELP!

HELP!

HELP!

HELP!

HELP!

HELP!

HELP!

Educate yourself

- Read CDC's "Pink Book" cover to cover
www.cdc.gov/vaccines/pubs/pinkbook/pink-chapters.htm
- Look for answers in the relevant ACIP recommendations
www.cdc.gov/vaccines/pubs/ACIP-list.htm
- Read IAC's "Ask the Experts" Q&As
www.immunize.org/askexperts
- Subscribe to *IAC Express* for weekly updates
www.immunize.org/subscribe

Need more help?

- Email CDC's experts: nipinfo@cdc.gov
- Call your state immunization coordinator (contact information can be found at www.immunize.org/coordinators)
- Contact your vaccine rep or call the manufacturer
- Email IAC: admin@immunize.org

The End

and, thank you!